



COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP
State Health Commissioner

Department of Health
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Manufacturer Agreement

Memorandum of Understanding and Agreement

This Agreement, made this 15th day of November, 2010, is by and between the Commissioner of Health and Consolidated Treatment Systems, Inc. "Manufacturer." The Commissioner delegates implementation and acceptance of this Agreement to the Division of Onsite Sewage and Water Services (DOSWS).

The Manufacturer agrees to test and evaluate the efficacy of Multi-Flo FTB-Series, the "Treatment Device" in accordance with the evaluation protocol set forth below. The Treatment Units will be jointly selected and agreed upon by the Manufacturer and DOSWS. The Manufacturer further agrees to:

1. Test and complete an evaluation (as described in this Agreement) of a minimum 20 Treatment Units within three years of the date that this Agreement is executed. The Manufacturer must conclude the evaluation on or before November 14, 2013.
 - i. Each of the 20 Treatment Units selected for evaluation must be designed and used for a single-family residential dwelling less than 1,000 GPD, used as expected for a permanently occupied home for 12-months.
 - ii. No evaluation or testing will be accepted for seasonal occupancy or seasonal rental use.
 - iii. The Manufacturer will contact DOSWS as soon as practical when a viable Treatment Unit for evaluation is installed. Upon notice by the Manufacturer, DOSWS will confirm whether the Treatment Unit will be selected.
 - iv. The Manufacturer will maintain an electronic database of Treatment Units selected for evaluation and report the database, along with associated influent and effluent results quarterly. The Manufacturer will retain copies of the Chain of Custody forms for sample collection, transport, and measurements and provide them to DOSWS within five days upon request.
 - v. Hire and use a third party, as described in this section and accepted by DOSWS, to collect a minimum of four consecutive quarterly influent and

effluent samples for 12 months on each of the 20 Treatment Units. All procedures to collect, transport, and measure samples, with proper chain of custody, must be conducted under the supervision of a faculty member in an appropriate program of an accredited college or university, a licensed professional engineer experienced in the field of sanitary engineering, or by a testing firm acceptable to DOSWS.

- vi. Bacterial counts shall be made using Standard Methods 9223, 9221 E, or 9222 D with sufficient dilution to report values up to approximately 200,000 organism/100mL. If adequate and continuous disinfection is provided, then measurement of bacterial counts is not required. If the installation complies with the vertical offset requirements for the dispersal of secondary effluent to the seasonal watertable or other soil wetness feature as specified in the *Regulations*, then disinfection is not required.
2. The Manufacturer will provide a copy of the contract with the third party, which must clearly describe the duties to be performed by both the third party and the Manufacturer. The Manufacturer and third party will provide a Quality Assurance and Quality Control (QA/QC) plan in the contract. The QA/QC plan will include information on the collection, transport and handling of samples and must be satisfactory to DOSWS.

The contract must specify when sample measurements will be sent to DOSWS and that all persons used to collect, transport, or test samples will be properly trained to perform the corresponding tasks. The contract must be provided at the time this Agreement is completed and must be acceptable to DOSWS.

- i. The third party agreed to is/are
3-Engineering, LLC, 1518 Willow Lawn Drive, Henrico, VA 23230.
- ii. If requested by DOSWS, the Manufacturer agrees that the third party will provide at least 72 hours notice before collecting samples and allow for joint collection with DOSWS, or its designee upon request.
- iii. The Manufacturer agrees to place and assure that at least two inspection and sampling ports are available to allow the third party to adequately sample for influent and effluent. Each inspection and sampling port must be located to accurately characterize the influent and effluent generated.
- iv. The Manufacturer agrees to test and report influent and effluent results as described above for the following constituents (unless specifically waived by DOSWS): BOD₅, TSS, Fecal Coliforms in cfu/100 ml or E.Coli (when disinfection is not provided), Dissolved Oxygen, Temperature, and pH.

Sometimes influent data that reflects the wastewater characteristics produced by the residential dwelling is not practical to collect. In such case, the Manufacturer will report influent from the recirculation tank.

If the influent does reflect the average or normal values for residential wastewater, then DOSWS may require additional testing or eliminate that specific residence from consideration as part of the evaluation.

3. Hire and use a lab certified and accepted by DOSWS to perform BOD₅, TSS, and fecal coliform measurements using the *Standard Methods for the Examination of Water and Wastewater* for influent and effluent, including any requirements set forth by the U.S. Environmental Protection Agency (USEPA). Composite or grab samples for TSS and BOD₅ may be used. Grab samples for fecal coliforms is required. The third party will directly report the results to DOSWS no later than the 15th day following completion of testing for any sample.
 - i. The certified lab is/are
 To Be Determined--Certified Laboratories will be identified in proximity to _____.
 installation sites to meet sampling, chain-of-custody, and time requirements.
4. Maintain an electronic database or spreadsheet of all system installations, with or without variances, and report the database to the Director, DOSWS by the 15th day of March, June, September, and December of each year the evaluation continues. The spreadsheet report will include the following information:
 - i. Sample results for influent and effluent.
 - ii. Interim observations about the Treatment Unit's performance with respect to the pass/fail criteria.
 - iii. Describe the dispersal design and offsets to soil limiting features for each system sampled.
5. Install no more than 30 Treatment Units per calendar year with the variances provided by this interim policy, for a maximum of 90 Treatment Units with the associated variances over the three year evaluation period. An unlimited number of Treatment Units is allowed without the associated variance(s).
6. The pass/fail criteria for effluent will be as follows:

	Log Transformed Upper 99% Confidence Interval Converted Back to Native Units
BOD ₅ (mg/l)	Less than or equal to 10 mg/l
TSS (mg/l)	Less than or equal to 10 mg/l
Fecal coliforms (cfu/100ml) or E.Coli	Less than or equal to 2,000 cfu/100ml

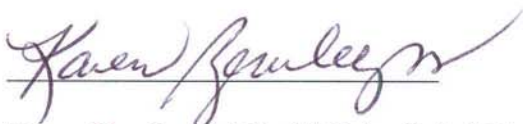
In return for the above considerations, DOSWS agrees to maintain a list of Treatment Units installed in Virginia and their sampling results. DOSWS will have three categories under which a Treatment Unit may be listed. The categories are as follows: "Completed testing and passed," "Did not pass/Did not complete testing," and "Evaluation Ongoing." The database and categories will be posted on the Virginia Department of Health's website.

This Agreement is binding upon both parties until new regulations to amend or replace the *Sewage Handling and Disposal Regulations*, 12 VAC 5-610, occurs, or is otherwise made unnecessary. Upon conclusion of the testing and evaluation in accordance with this Agreement, DOSWS will render a case decision regarding whether the Treatment Unit has met the influent and effluent performance expectations.

If the case decision affirms that the Treatment Unit met the pass/fail criteria, then the Manufacturer is no longer required to continue the evaluation. Alternatively, if DOSWS finds the Treatment Unit did not meet the performance standards, then the Manufacturer will have 30 days to challenge the decision before the Manufacturer and Treatment Device are removed from being listed under GMP #147. Without listing, owners of Treatment Units will not have access to the variances permitted by GMP #147. If the Manufacturer cannot continue or decides not to continue the evaluation, the Manufacturer will provide DOSWS with 30 days written notice. DOSWS, in its sole discretion, will decide whether to remove sampling results for the Treatment Unit from its website.

This Agreement may be updated, amended, modified, or replaced upon 30 days written notice of either party or with the consent of both parties. The DOSWS may update, amend, modify, or replace the Agreement on behalf of the Commissioner.

Read, Understood, and Agreed to:



Karen Remley, M.D., M.B.A., F.A.A.P.
State Health Commissioner

Manufacturer